

REMARKS

This Amendment is in response to the Office Action dated **July 6, 2009**. Each issue in the Office Action is addressed below.

§102 Rejections

Claims 21-25, 29-30 and 39-41 were rejected under 35 U.S.C. §102(b) as being anticipated by Vigil et al. (US 5320634). A full account of the rejection is found in paragraph 3 on page 2 of the Office Action.

Although Applicant disagrees with the rejection, independent claims 21, 29 and 41 have been amended to further distinguish them from the cited reference. The independent claims have been amended to incorporate the subject matter of claim 25. As such, each of the independent claims, 21, 29 and 41, require that “each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure.” At least this element is not disclosed in Vigil et al.

The rejection does appear to address the subject matter of claim 25 at the end of numbered paragraph 3 in the rejection. In referring to Vigil et al. (Figure 3B), it is stated that “...the wings are capable of overlap when compressed more completely than shown in figure 3B.” However, this assertion is unsupported by the reference and it is improper speculation based on figure 3B (shown below).

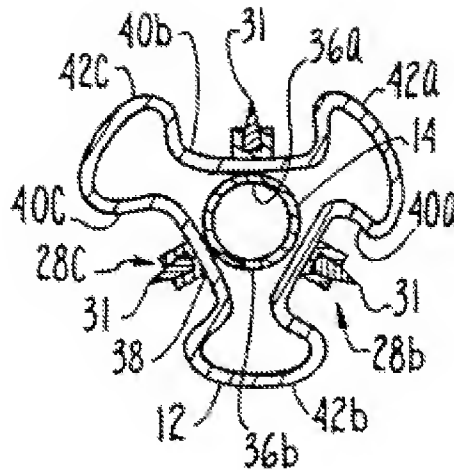


Fig. 3B

Vigil et al. states that Fig. 3B shown above represents the balloon's "deflated configuration prior to insertion into a blood vessel" (see col. 5, lines 3-4). It does not show any of the wings overlapping. It is more than speculation from the figure that the folds are even capable of overlapping, while at the same time maintaining a first and second wing for each of the "structures", as required by the independent claims. From the figures, it appears that a speculative forced overlapping of any of the folds would destroy any speculative pairs of first and second wings established in a "structure".

The text of Vigil et al. offers no support for the speculation that the folds/flaps 42a, 42b, 42c are capable of overlapping while maintaining "first and second wings" for each structure. The reference only indicates that the folds/flaps 42a, 42b, 42c bunch up between the atherotomes 28 while the atherotomes collapse at the creases 38 (see col. 2, lines 64-67) such that the fold/flaps 42a, 42b, 42c are higher than the atherotomes 28 so that the atherotomes 28 don't contact the vessel wall. There's not even any indication that the folds/flaps can cover the atherotomes.

In column 2, starting on line 30, in Vigil et al., it is stated:

Prior to insertion of the device into the vessel, the balloon is deflated. When deflated, each atherotome mounted on the outer surface of the deflated balloon is aligned along the longitudinal axis of the catheter and is circumferentially equidistant from each adjacent atherotome. Further, each atherotome is attached to the balloon along a crease in the balloon that is longitudinal to the axis

of the catheter. As attached, the cutting structure of each atherotome projects radially outward from the axis of the catheter.

It is further stated starting on line 39 that:

Retraction of the atherotomes toward the longitudinal axis of the catheter during deflation of the balloon forms a flap in the balloon *between adjacent atherotomes*. (emphasis added)

It states that, in the deflated condition, the flaps are *between* adjacent atherotomes. It does not indicate that the flaps cover the atherotomes or overlap one another.

The text further states starting at line 45 that:

In such a deflated insertion configuration, the folded edges and flaps, rather than the cutting structure of the atherotomes, contact the vessel wall as the device is manipulated into position adjacent a stenotic site, thus shielding the unoccluded vessel walls from contact with the cutting edges of the atherotomes.

Guided by figure 3B, we see that the “shielding” occurs at least because the atherotomes fall down into their creases while the flaps are elevated above them, thus preventing contact between the cutting structure and the vessel. There is no indication of overlapping or that the flaps are long enough to overlap one another or the necessity of overlapping of flaps for shielding the cutting structure. The relative heights of the flaps relative to the cutting structures perform the function. Further in column 5, starting at lines 15-18, the reference states:

In pairs these concave sides 40a,b,c form flaps 42a, 42b, 42c which are actually folds in the surface of the balloon 12 *between* creases 38a, 38b, 38c respectively. (emphasis added)

The text states that, in the deflated condition, the folds in the surface of the balloon are *between* creases, from which the atherotomes extend. It does not indicate that the folds cover the atherotomes or overlap one another.

The rejection fails at least because it does not provide for each and every element of the claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). It has at least not been

shown that Vigil et al. disclose that “each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure”, as required by independent claims 21, 29 and 41.

As mentioned above, in referring to Vigil et al. (Figure 3B), it is stated in the rejection that “...the wings are *capable* of overlap when compressed more completely than shown in figure 3B.” (Emphasis added) However, this assertion is unsupported by the reference and it is improper speculation based on figure 3B. It also does not show that the device of Vigil et al. inherently discloses “each second wing of the structures is in an overlapping relationship with a first wing of an adjacent structure”, as required by independent claims 21, 29 and 41.

As stated in MPEP 2112 (IV), the rejection must provide rationale or evidence tending to show inherency. MPEP 2112 (IV) further states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ... "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

Speculating from figure 3B of the cited reference that “[t]he wings are capable of overlap” without figure 3B showing any overlap or any support from the text of the reference, the rejection merely asserts that “a certain result or characteristic may occur or be present”. This is not sufficient to establish the inherency of that result or characteristic. (See above and *In re*

Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)) The rejection does not make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill to establish inherency. The assertion of the rejection is established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. (See above and *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999))

The rejection reads into the reference what is not clearly there nor needed to perform its function and it does not establish inherency. As such, the reference does not clearly provide the asserted teaching and the rejection is improper. Withdrawal of the rejection is therefore respectfully requested.

Miscellaneous

In additions to the above mentioned amendments, claim 25 has also been amended and claims 43-47 have been added. No new matter has been added

The assertions in the Office Action that are not specifically addressed above have not been specifically addressed because it is unnecessary and moot in light of Applicant's comments and amendments shown above. It should not be construed that Applicant acquiesces to the unaddressed assertions. Applicant reserves the right to address these assertions at a later date if needed.

Conclusion

Based on at least the above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 21-25, 29-30, 39-41 and 43-47 is requested. Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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